[3510-16-P]

DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

[Docket No.: PTO-C-2012-0049]

Notice of Public Roundtable on Genetic Diagnostic Testing

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Notice of public roundtable.

SUMMARY: The United States Patent and Trademark Office ("USPTO") is interested in gathering additional information on independent second opinion genetic diagnostic testing for purposes of preparing a report on the subject as required by the America Invents Act ("AIA" or "Act"). To assist in gathering this information, the USPTO invites the public to attend a roundtable focused on genetic diagnostic testing.

PUBLIC ROUNDTABLE: The USPTO will hold a public roundtable in support of the genetic testing study. The roundtable will be held on Thursday, January 10, 2013, beginning at 1:00 p.m. Eastern Standard Time (EST) and ending at 4:00 p.m. (EST) in Alexandria, Virginia.

Those wishing to share commentary at the roundtable must request an opportunity to do so in writing no later than December 20, 2012. The request must include the following: (1) the name of the person wishing to share commentary; (2) the person's contact information (telephone number and e-mail address); (3) the organization(s) the person represents, if any; and (4) an indication of the amount of time requested for the commentary. Requests to share commentary must be submitted by e-mail to Saurabh Vishnubhakat at saurabh.vishnubhakat@uspto.gov. Based upon the requests received, an agenda will be sent to all requesters and posted on the USPTO Internet Web site (address: www.uspto.gov/americainventsact).

Speakers sharing commentary at the roundtable must submit a document explaining their position for inclusion in the record of the proceedings no later than thirty days after the roundtable. Written commentary should not exceed 25 pages using at least 12-point and double-spaced font. Because written commentary will be made available for public inspection, information that a speaker does not desire to be made public, such as a telephone number, should not be included in the written comments.

The public roundtable will be available via Web cast. Information about how to access the Web cast will be posted on the USPTO's Internet Web site (address: http://www.uspto.gov/americainventsact) before the public roundtable.

A transcript of the roundtable will be available on the USPTO Internet Web site (address: www.uspto.gov/americainventsact) shortly after the roundtable.

ADDRESSES: The public roundtable will be held at the USPTO in the Madison Auditorium on the concourse level of the Madison Building, located at 600 Dulany Street, Alexandria, Virginia 22314.

FOR FURTHER INFORMATION CONTACT: Saurabh Vishnubhakat, Expert Advisor, Office of Chief Economist, by telephone at 571-272-9300, or by e-mail at saurabh.vishnubhakat@uspto.gov.

SUPPLEMENTARY INFORMATION:

Section 27 of the AIA charges the Director of the USPTO with delivering to Congress a study and recommendations no later than nine months after the enactment of the Act (i.e., by June 15, 2012) regarding independent second opinion genetic diagnostic testing where patents and exclusive licenses exist that cover primary genetic diagnostic tests. Congress has mandated that the study include an examination of at least the following:

(1) The impact that the current lack of independent second opinion testing has had on the ability to provide the highest level of medical care to patients and recipients of genetic diagnostic testing, and on inhibiting innovation to existing testing and diagnoses;

(2) The effect that providing independent second opinion genetic diagnostic testing would have on the existing patent and license holders of an exclusive genetic test;

(3) The impact that current exclusive licensing and patents on genetic testing activity has on the practice of medicine, including but not limited to the interpretation of testing results and performance of testing procedures; and

(4) The role that cost and insurance coverage have on access to and provision of genetic diagnostic tests.

In the Act, Congress defined the term "confirming genetic diagnostic test activity" to mean the performance of a genetic diagnostic test, by a genetic diagnostic test provider, on an individual solely for the purpose of providing the individual with an independent confirmation of results obtained from another test provider's prior performance of the test on the individual.

Recognizing the diversity and complexity of the public policy issues surrounding independent second opinion genetic diagnostic testing, the USPTO conducted a thorough review of the academic and scientific literature, took notice of several published reports, and actively sought diverse and sophisticated input from the public. In that last regard, the Office published a notice in the *Federal Register* and on the USPTO public Web site dedicated to AIA implementation (AIA micro-site), seeking written comments and announcing two public hearings for this study. *See Request for Comments and Notice of Public Hearings on Genetic Diagnostic Testing*, 77 FR 3748 (Jan. 25, 2012). The Office also provided the public with a dedicated e-mail address and a contact person in the USPTO to receive comments.

As announced in the *Federal Register* and on the AIA micro-site, the Office held two public hearings dedicated to taking public comment for this report. The first occurred at the USPTO

headquarters in Alexandria, Virginia, on Thursday, February 16, 2012, and the second took place at the University of San Diego School of Law in San Diego, California, on Friday, March 9, 2012. At the hearings, witnesses provided pre-scheduled testimony, and members of the audience provided spontaneous testimony. Representatives from the USPTO attended the hearings and actively questioned all witnesses. Also, witnesses exchanged comments with the audience.

In the final days before the deadline for receipt of written comments, the Supreme Court of the United States issued two rulings with potential ramifications for the present study. The first was a memorandum opinion in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289 (2012). The second was an order in *Association for Molecular Pathology v. Myriad Genetics*, 132 S. Ct. 1794 (2012), granting the petition for a writ of certiorari, vacating the decision of the United States Court of Appeals for the Federal Circuit (CAFC), and remanding the case for reconsideration in light of the *Mayo* decision. Accordingly, the USPTO published a notice on the AIA micro-site seeking additional public input, within ten calendar days, regarding the impact of the Supreme Court's actions on independent second opinion genetic diagnostic testing.

Through the *Federal Register* notice and hearings, the Office received twenty-seven sets of written comments and testimony from eighteen witnesses. Respondents with written comments, many of whom also testified, included four U.S. intellectual property organizations, thirteen U.S.

companies and organizations, three U.S. patent practitioners, and seven members of the public speaking as individuals.

On August 28, 2012, the Department of Commerce sent a letter to the House and Senate Judiciary Committee leadership updating them on the status of the genetic testing report. The letter stated in part: "Given the complexity and diversity of the opinions, comments, and suggestions provided by interested parties, and the important policy considerations involved, we believe that further review, discussion, and analysis are required before a final report can be submitted to Congress." After this additional public roundtable, the USPTO will follow next steps and fulfill its obligation to Congress.

ISSUES FOR COMMENT: The USPTO seeks comments on how to address the issue of independent second opinion genetic diagnostic testing and its relationship to medical care and medical practice, the rights of innovators, and considerations relevant to medical costs and insurance coverage. The issues enumerated below are as posed in the AIA and serve as a preliminary guide to aid the USPTO in collecting further relevant information and to evaluate possible administrative or legislative recommendations that may be provided to Congress. The tenor of the following issues should not be taken as an indication that the USPTO has taken a position or is predisposed to any particular views. The public is invited to address any or all of these issues. The public also is invited to provide input on other issues believed to be relevant to the scope of the study in addition to those listed below.

(1) The impact that the current lack of independent second opinion testing has had on the ability to provide the highest level of medical care to patients and recipients of genetic diagnostic testing, and on inhibiting innovation to existing testing and diagnoses;

(2) The effect that providing independent second opinion genetic diagnostic testing would have on the existing patent and license holders of an exclusive genetic test;

(3) The impact that current exclusive licensing and patents on genetic testing activity has on the practice of medicine, including but not limited to the interpretation of testing results and performance of testing procedures; and

(4) The role that cost and insurance coverage have on access to and provision of genetic diagnostic tests.

Date: _November 21, 2012

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David J. Kappos
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

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